Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MEDRAD, INC.	)	
Plaintiff,	)	
vs	)	
	)	CIVIL ACTION NO. 01-1997-DEZ
TYCO HEALTHCARE GROUP LP,	)	
MALLINCKRODT, INC.	)	Judge Donald E. Ziegler
LIEBEL-FLARSHEIM CO., and	)	
NEMOTO KYORINDO CO., LTD.	)	
	)	
Defendants.	)	

DEFENDANTS', TYCO HEALTHCARE GROUP LP, MALLINCKRODT, INC. AND LIEBEL-FLARSHEIM CO., ANSWER AND COUNTERCLAIM TO SECOND AMENDED COMPLAINT

Defendants, Tyco Healthcare Group LP (hereinafter ATyco Healthcare@), Mallinckrodt, Inc. (hereinafter AMallinckrodt@), and Liebel-Flarsheim Company (hereinafter AL-F@) (hereinafter referred to collectively as AL-F@), through their attorneys hereby answer plaintiff=s Second Amended Complaint as follows:

1. L-F admits that the plaintiff=s Second Amended Complaint purports to state claims under the patent laws of the United States, but denies that plaintiff has any such claims or that any such claims are justified.

2. L-F admits that this Court has subject matter jurisdiction over the claims brought in the present action.

3. L-F admits that venue is proper as to L-F in this judicial district. L-F denies that acts of infringement have been committed in this judicial district. Since

the allegations that venue is proper for defendant Nemoto is not directed at L-F, no answer is required.

4. On information and belief, L-F admits the allegations of paragraph 4 of plaintiff=s Second Amended Complaint.

5. L-F admits the allegations of paragraph 5 of plaintiff=s Second Amended Complaint.

6. L-F admits the allegations of paragraph 6 of plaintiff=s Second Amended Complaint.

7. L-F admits the allegations of paragraph 7 of plaintiff=s Second Amended Complaint.

8. L-F admits that Nemoto is a foreign corporation located in Tokyo, Japan, but otherwise denies the allegations of paragraph 8 of plaintiff=s Second Amended Complaint.

9. L-F admits that United States Patent No. 5,808,203 (hereinafter Athe >203 patent@) shows on its face that it issued on September 15, 1998; that the >203 patent is entitled AFluid Pressure Measurement Devices;@ and that a copy of the >203 patent is attached as Exhibit A to the Second Amended Complaint. With respect to the remaining allegations of paragraph 9 of plaintiff=s Second Amended Complaint, L-F is without knowledge sufficient to form a belief as to the truth thereof, and therefore, denies same and puts plaintiff to its proof.

10. L-F admits that United States Patent No. 6,339,718 (hereinafter Athe >718 patent@) shows on its face that it issued on January 15, 2002; that the >718 patent is entitled AProgrammable Injector Control;@ and that a copy of the >718 patent is

attached as Exhibit B to the Second Amended Complaint. With respect to the remaining allegations of paragraph 10 of plaintiff=s Second Amended Complaint, L-F is without knowledge sufficient to form a belief as to the truth thereof, and therefore, denies same and puts plaintiff to its proof.

11. L-F admits that United States Patent No. Re 37,602 (hereinafter Athe >602 reissue patent@) shows on its face that it reissued on March 26, 2002; that the >602 patent is entitled APatient Infusion System For Use With MRI;@ and that a copy of the >602 reissue patent is attached as Exhibit C to the Second Amended Complaint. With respect to the remaining allegations of paragraph 11 of plaintiff=s Second Amended Complaint, L-F is without knowledge sufficient to form a belief as to the truth thereof, and therefore, denies same and puts plaintiff to its proof.

12. L-F denies the allegations of paragraph 12 of plaintiff=s Second Amended Complaint.

13. L-F denies the allegations of paragraph 13 of plaintiff=s Second Amended Complaint.

14. L-F denies the allegations of paragraph 14 of plaintiff=s Second Amended Complaint.

15. L-F admits that it entered into an exclusive supply contract for the purchase of medical injector components manufactured by Nemoto in Japan but otherwise denies the allegations of paragraph 15 of plaintiff's Second Amended Complaint.

16. L-F admits that Mallinckrodt and L-F have imported medical injector components manufactured by Nemoto in Japan that L-F incorporated into

equipment sold in the United States under the designation OptistarJ but otherwise denies the allegations of paragraph 16 of plaintiff=s Second Amended Complaint.

17. L-F denies the allegations of paragraph 17 of plaintiff=s Second Amended Complaint.

18. L-F denies the allegations of paragraph 18 of plaintiff=s Second Amended Complaint.

AFFIRMATIVE DEFENSES

By and for its affirmative defenses, L-F states:

FIRST AFFIRMATIVE DEFENSE

19. The Second Amended Complaint fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

20. Upon information and belief, and as will likely be supported by evidence after a reasonable opportunity for further investigation and discovery, those claims of the >203 patent asserted by Medrad against L-F in this litigation are invalid for failure to comply with the conditions and requirements for patentability specified in Title 35 U.S.C., including, but not limited to, 35 U.S.C. ' ' 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE

21. Upon information and belief, and as will likely be supported by evidence after a reasonable opportunity for further investigation and discovery, the >718 patent is invalid for failure to comply with the conditions and requirements for patentability specified in Title 35 U.S.C., including, but not limited to, 35 U.S.C. ' ' 102, 103, and/or 112.

FOURTH AFFIRMATIVE DEFENSE

22. Upon information and belief, and as will likely be supported by evidence after a reasonable opportunity for further investigation and discovery, the >602 reissue patent is invalid for failure to comply with the conditions and requirements for patentability specified in Title 35 U.S.C., including, but not limited to, 35 U.S.C. ' ' 102, 103, 112 and/or 251.

FIFTH AFFIRMATIVE DEFENSE

23. L-F has not infringed the >203 patent and is not liable for infringement thereof.

SIXTH AFFIRMATIVE DEFENSE

24. L-F has not infringed the >718 patent and is not liable for infringement thereof.

SEVENTH AFFIRMATIVE DEFENSE

25. L-F has not infringed the >602 reissue patent and is not liable for infringement thereof.

EIGHT AFFIRMATIVE DEFENSE

26. Medrad is barred by the doctrine of intervening rights, as set forth in 35 U.S.C. § 252, from precluding defendants from manufacturing, using, offering for sale, selling and/or importing into the United States the Optistar MR Contrast Delivery System.

NINTH AFFIRMATIVE DEFENSE

27. The asserted claims of the '602 reissue patent are invalid and/or void because the alleged error that was the subject of the '602 reissue patent is not the type of error that may be corrected by reissue.

TENTH AFFIRMATIVE DEFENSE

28. On information and belief, the '718 patent is unenforceable due to inequitable conduct committed by Medrad and/or individuals on behalf of Medrad by the knowing, willful and deliberate omission and misrepresentation of facts material to the prosecution of the '718 patent to the United States Patent and Trademark Office ("USPTO"), which omissions and misrepresentations were made with the intent to mislead and/or deceive the USPTO Examiner.

29. Medrad manufactures, markets and sells in the United States medical injectors for use in connection with magnetic resonance imaging (MRI) procedures, which Medrad markets under the name Spectris MR Injector. The Spectris MR Injector received FDA approval in 1995, and Medrad introduced it commercially in United States in the spring of 1996. Accordingly, the Spectris MR Injector constitutes prior art to the '718 patent at least under 35 U.S.C. § 102(b).

30. Medrad has published an Operation Manual for the Spectris MR Injector that describes, among other things, the basic operations, screen messages, configuration screens and specifications for the Spectris MR Injector. The Spectris MR Operation Manual constitutes prior art to the '718 patent at least under 35 U.S.C. § 102(b).

31. Specifically:

a. The application leading to issuance of the '718 patent, Application No. 09/365,278, was filed July 30, 1999, originally with three claims. Claim 1 was directed to an apparatus for controlling a patient injector system comprising means for establishing a first phase of an injection protocol comprising one of: a contrast medium phase and a flushing medium phase and means for establishing a subsequent second phase of said protocol comprising one of: a contrast medium phase and a flushing medium phase.

Claim 2 was directed to apparatus comprising means for establishing a first phase comprising one of a contrast medium phase and a flushing medium phase and means for establishing a second hold phase.

Claim 3 was directed to an MRI injector comprising means for establishing a first phase, means for establishing a second phase and means for establishing a pause phase between the first and second phases.

b. Claim 1 was filed even though Medrad had acknowledged its own Spectris MR Injector as prior art and described that injector as having means for establishing a first contrast medium phase and a second flushing medium phase. Thus, claim 1 as filed was anticipated by Medrad's own prior art.

c. On January 19, 2000, Medrad filed a Preliminary Amendment canceling claims 1-3 and adding new claims 4-23. Claim 4 was directed to a fluid injection apparatus comprising at least one drive mechanism, at least two fluid containers, one containing contrast medium and the other containing a flushing medium, and a "control device" to selectively program a plurality of phases of an injection procedure, each of the phases comprising one of at least a contrast medium phase and a flushing medium phase. The term "plurality" requires only at least two members. *York Products, Inc. v Central Tractor Farm & Family Center*, 99 F.3d 1568, 1575 (Fed. Cir. 1996). Thus, claim 4 was again anticipated by the Spectris MR Injector, which could be selectively programmed for a contrast medium phase and a subsequent flushing medium phase.

d. Claim 8 depended from claim 4 and recited that each of the plurality of phases comprised at least one of a contrast medium phase, a flushing medium phase and a KVO (keep vein open) phase. Thus, although claim 8 permitted either or both of the phases to be a KVO phase, it did not require a KVO phase and, thus, did not distinguish over the Spectris MR Injector.

Claim 11 depended from an independent claim 9, which stated that the second phase was a pre-programmed hold phase, and stated that KVO occurs during the hold phase. The Spectris MR Injector included both a KVO and hold phase. Accordingly, claim 11 did not distinguish over the Spectris MR Injector.

Claim 19 depended from an independent claim 18 and added selectively programming a KVO phase to selectively programming a first and second phase, either of which comprised one of a contrast medium phase and a flushing medium phase. Claim 19 did not distinguish over the Spectris MR Injector.

e. In a first Office Action dated December 22, 2000, the Examiner rejected all claims other than claims 8, 11 and 19, which were objected to as depending from rejected independent claims but were deemed allowable if written in independent form.

f. The claims that were rejected were rejected as being anticipated by U.S. Patent No. 5,472,403 to Cornacchia. The Examiner stated that the reference taught a device for automatic injection of a radionuclide wherein the first phase comprises a flushing phase and the second phase comprises a contrast medium phase and wherein the device had a pre-programmed hold phase during injection. (The reference actually disclosed the first phase as the contrast medium phase and the second phase as a flushing phase.) The Examiner applied no prior art disclosing a KVO phase to the claims.

g. An interview was held on March 16, 2001. The Interview Summary states: "Applicants agree to modify claims toward means-function/step-function. Examiner maintained rejection, as it reads on the claims. Structural limitation non-limiting. Proposed amendment was discussed."

h. In an Amendment dated May 25, 2001, Medrad canceled claims 4-23 and added claims 24-103. New claim 24 was simply claim 8 written in independent form. This claim did not distinguish over the Spectris MR Injector. Nor did it distinguish over the Cornacchia reference cited by the Examiner. Medrad, in its accompanying Remarks, did not explain how new claim 24 was patentable but merely noted that previously pending claim 8 had already been indicated as being allowable. All claims were then renumbered and allowed. Claim 24 became patent Claim 1.

i. The Spectris MR Injector allows for programming of a variety of injection phases. As recited at pages 2-7 of the Spectris MR Operation Manual, there are two syringes, one containing a contrast medium and one containing a flushing medium, and two phases for each syringe, or a maximum of four phases available for programming. For example, the contrast syringe A could be used alone with KVO, or the contrast syringe A could be used in one or two phases followed by the flushing syringe B in one or two phases, again with KVO.

The KVO function is described at pages 2-12. The manual states:

> The KVO function provides fluid delivery at a very slow flow rate prior to the beginning of an injection, after the successful completion of a single injection, between multiple injections and during HOLD intervals.

j. At least claims 1, 2, 4, 5, 8, 48, 49 and 50 of the '718 patent are anticipated by the Spectris MR Injector and the Spectris MR Injector Operation Manual.

k. In the May 25, 2001 Amendment, Medrad's representatives made numerous and lengthy arguments to distinguish the newly presented claims 24-103 over the single reference applied by the Examiner, i.e., the Cornacchia patent. For example, in discussing application claim 32, Medrad's representatives distinguished Cornacchia with these words:

> Particularly, Cornacchia appears to contemplate only one conceivable protocol, namely, that of injecting radionuclide solution followed by an injection of saline, or flush, solution. Claim 32, on the other hand, recites that, through available structure, not only are three phases of injection procedure available, but a third phase is programmable as a phase other than a flushing medium phase....
>
> It is clear that analogous structure, available to perform the specific function of programming a third phase of an injection procedure as a phase other than a flushing medium phase, is neither taught nor suggested by Cornacchia. For one, Cornacchia does not even contemplate the possibility of a third phase.

l. Medrad, in applying the claims of the '718 patent to the Optistar MR injector, asserts KVO as a "phase". The quotation above from pages 2-12 of the Spectris MR Injector Operation Manual shows that the Spectris MR Injector was capable of being programmed with a third phase as Medrad asserts the claim to mean, e.g., a first phase being a contrast medium injection, a second phase being

KVO and third phase being contrast medium, i.e., "a phase other than a flushing medium phase."

m. As another example, Medrad's representatives argued with respect to Claim 33 that: "There is nothing in Cornacchia to teach or suggest that the device disclose therein could or should be capable of performing such a task [i.e., programming a first phase of an injection procedure as a phase other than a contrast medium phase.]." Medrad, in applying the claims of the '718 patent to the Optistar MR injector, asserts KVO as a "first phase." The Spectris MR Injector, however, has exactly this capability.

n. Throughout the May 25, 2001 Amendment additional representations of like ilk were made by Medrad's representatives. The Examiner relied on these representations in allowing claims 24-103 to issue. For example, amendment claim 32 issued as patent claim 9, and amendment claim 33 issued as patent claim 10. Each of these representations was, on information and belief, knowingly, willfully and deliberately made by Medrad to the USPTO Examiner knowing full well that the prior art Spectris MR Injector had exactly the capability that Medrad argued Cornacchia did not have with the intent of deceiving the Examiner.

o. On information belief, Medrad, including Gregory L. Bradley, Esq., failed to disclose to the USPTO that the arguments made to distinguish amendment claims 24-103 from the Cornacchia patent could not distinguish those claims from the Medrad MR Injector and the Medrad MR Injector Operation Manual

because it knew that had it disclosed this information to the Examiner the '718 patent would not have issued.

ELEVENTH AFFIRMATIVE DEFENSE

32. On information and belief, the '602 reissue patent is unenforceable due to inequitable conduct committed by Medrad and/or individuals on behalf of Medrad by the knowing, willful and deliberate omission and misrepresentation of facts material to the prosecution of the '036 patent, the '648 reissue patent and/or the '602 reissue patent to the United States Patent and Trademark Office ("USPTO"), which omissions and misrepresentations were made with the intent to mislead and/or deceive the USPTO Examiner. Specifically:

a. On information and belief, during prosecution of the '036 patent, Medrad and/or individuals on behalf of Medrad knowingly, willfully and deliberately misrepresented and failed to disclose to the USPTO prior commercial public uses and knowledge of products and prior publications anticipating claims or rendering obvious the '036 patent, including, but not limited to, prior commercial public uses of the injector system identified and/or referred to in the 1991 publication, Saini et al., "*Technical Report: In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance of Contrast Media*", Investigative Radiology, Vol. 26/No. 8 Aug. 1991, pp. 748-51 ("Saini Article");

b. On information and belief, during prosecution of the '036 patent, Medrad and/or individuals on Medrad's behalf knowingly, willfully and deliberately failed to inform the USPTO of the public use and knowledge of an MRI

contrast delivery system more than one year before the filing date of the '036 patent that was disclosed in the 1992 publication, "*Detection of Acute Vascular Necrosis of the Femoral Head in Dogs; Dynamic Contrast-Enhanced MR Imaging vs. Spin-Echo and Stir Sequences*" found in AJR: 159, pp. 1255-61, Dec. 1992 ("AJR Article"), and of the medical injector system for use in MRI procedures developed by Medrad for display and/or displayed at the 1988 Radiological Society of North America Trade Show as referred to in "*Market Scan*", Diagnostic Imaging, September 1988, pp. 57-63 ("Market Scan Article");

c. On information and belief, during prosecution of the '036 patent, Medrad and/or individuals on Medrad's behalf knowingly, willfully and deliberately failed to disclose to the USPTO numerous public uses and public knowledge of the MRI injectors being claimed in the '036 patent more than one year before the filing date of the '036 patent, including, without limitation, the public uses and/or public knowledge regarding the MRI injector units provided by Medrad to major hospitals, university medical centers and medical institutes prior to November 26, 1992;

d. On information and belief, during prosecution of the '036 patent, Medrad and/or individuals on Medrad's behalf knowingly, willfully and deliberately failed to cite to the USPTO Medrad's Magnetic Resonance Injector Operation Manual, dated November 17, 1987 ("1987 Operation Manual") which, on information and belief, Medrad submitted to the Food & Drug Administration in connection with 510(k) Number K873173 for the "Medrad MRI Injection System";

e. On information and belief, during prosecution of the '036 patent Medrad and/or individuals on Medrad's behalf knowingly, willfully and deliberately failed to disclose to the USPTO that, prior to November 26, 1992, Medrad offered for sale and sold MRI injectors to Squibb Diagnostics, a division of E. R. Squibb & Sons, Inc., that anticipated the claims of the '036 patent;

f. During prosecution of the '648 reissue patent, although Medrad now cited to the USPTO the Saini Article, on information and belief, Medrad and/or individuals on behalf of Medrad knowingly, willfully and deliberately failed to disclose to the USPTO that the medical injector that was the subject of the Saini Article was a Medrad Mark V medical injector, which included two syringes, and Medrad failed to disclose to the USPTO that the communication link between the system controller and the medical injector powerhead was substantially non-reactive with the magnetic field of the imaging system as Medrad now asserts that term means;

g. On information and belief, during prosecution of the '648 reissue patent, Medrad and/or individuals on behalf of Medrad knowingly, willfully and deliberately failed to cite to the USPTO the Medrad "The First and Only True Injection System" Mark V System Brochure, dated 1988, which brochure shows that the Mark V injector (such as the injector referred to in the AJR Article, the injector system developed for display and/or displayed at the 1988 Radiological Society of North America Trade Show as referred to in the Market Scan article, and/or as referred to in the Saini Article), was adapted to include two syringes mounted thereon. Counsel for Medrad prosecuting the '648 reissue patent, Gregory L. Bradley,

Esq., was well aware of this brochure during the prosecution of the application resulting in the '648 reissue patent as he cited it during the prosecution of application serial no. 08/901,602, which application was filed with the USPTO on July 28, 1997;

h. On information and belief, during prosecution of the '648 reissue patent, Medrad and/or individuals on Medrad's behalf continued to knowingly, willfully and deliberately fail to cite to the USPTO the 1987 Operation Manual;

i. On information and belief during prosecution of the '648 reissue patent, Medrad and/or individuals on behalf of Medrad continued to knowingly, willfully and deliberately fail to disclose to the USPTO that Medrad MRI contrast delivery systems installed at major hospitals, university medical centers and medical institutes more than one year before the filing date of the '036 patent had a communication link between the system controller and the injection control unit that was adapted to be substantially non-reactive with the magnetic field of the imaging system as Medrad now asserts that term means;

j. On information and belief, during prosecution of the '648 reissue patent, Medrad and/or individuals on Medrad's behalf continued to knowingly, willfully and deliberately fail to disclose to the USPTO that, prior to November 26, 1992, Medrad offered for sale and sold to Squibb Diagnostics MRI injectors that anticipated the claims of the '036 patent and that anticipated the claims of the '648 reissue patent;

k. On information and belief, during prosecution of the '602 reissue patent, Medrad and/or individuals on behalf of Medrad continued to

knowingly, willfully and deliberately fail to disclose to the USPTO that the medical injector that was the subject of the Saini Article was a modified Medrad Mark V medical injector, which included two syringes, and Medrad continued to fail to disclose to the USPTO that the communication link between the system controller and the medical injector powerhead was substantially non-reactive with the magnetic field of the imaging system as Medrad now asserts that term means;

l. On information and belief, during prosecution of the '602 reissue patent, Medrad and/or individuals on behalf of Medrad continued to knowingly, willfully and deliberately fail to disclose to the USPTO that Medrad MRI contrast delivery systems installed more than one year before the filing date of the '036 patent at major hospitals, university medical centers and medical institutes had a communication link between the system controller and the injection control unit that was adapted to be substantially non-reactive with the magnetic field of the imaging system as Medrad now asserts that term means;

m. On information and belief, during prosecution of the '602 reissue patent although Medrad cited to the USPTO certain of the prior art identified by the respondents in the action of *In re Certain Magnetic Resonance Injection Systems, Components Thereof and Molds Therefore*, Investigation No. 337-TA-434 (United States International Trade Commission) ("the ITC Action"), and identified to the USPTO the existence of the ITC Action and another copending action (*Medrad, Inc. v. Nemoto Kyorindo Company, Ltd., et al.*, Case No. 00-799 (W.D. Pa.)), Medrad failed to comply with the provisions of MPEP § 1442.04 and MPEP § 2001.06(c). Pursuant to MPEP § 1442.04:

> When applicant notifies the Office of the existence of the litigation, enough information should be submitted so that the Office can reasonably evaluate the need for asking for further materials in the litigation. Note that the existence of supporting materials which may substantiate allegations of invalidity should, at least, be fully described and preferably submitted.

Similarly, MPEP § 2001.06(c) provides, in relevant part:

> Where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. patent and Trademark Office. Examples of such material information include evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of "fraud" "inequitable conduct" and "violation of duty of disclosure." . . .
>
> . . . The details and documents from the litigation, insofar as they are "material to patentability" of the reissue application as defined in 37 CFR 1.56, should accompany the application as filed, or be submitted as promptly thereafter as possible. . . .
>
> For example, the defenses raised against validity of the patent, or charges of "fraud" or "inequitable conduct" in the litigation, would normally be "material to the examination" of the reissue application. It would, in most situations, be appropriate to bring such defenses to the attention of the Office by filing in the reissue application a copy of the court papers raising such defenses. At a minimum, the applicant should call the attention of the Office to the litigation, the existence and the nature of any allegations relating to validity and/or "fraud," or "inequitable conduct" relating to the original patent, and the nature of litigation materials relating to these issues. Enough information should be submitted to clearly inform the Office of the nature of these issues so that the Office can intelligently evaluate the need for further materials in the litigation.

Although Medrad identified the litigations to the USPTO during the prosecution of the '602 reissue patent, on information and belief, Medrad and/or individuals

on behalf of Medrad knowingly, willfully and deliberately failed to inform the USPTO of possible public uses and of the allegations of invalidity and of fraud and inequitable conduct raised by the respondents in the ITC Action by failing to provide to the USPTO copies of the Response of Liebel-Flarsheim Company, Mallinckrodt Inc. (Del.) and Mallinckrodt Inc. (NY) to the Verified Complaint under § 337 of the Tariff Act of 1930, as amended, and Notice of Investigation at Fifth Affirmative Defense, ¶ 71, Respondents' Liebel-Flarsheim Company, Inc.'s, Mallinckrodt Inc.'s (NY) and Mallinckrodt Inc.'s (Del.) Responses to Complainant Medrad's First Set of Interrogatories (Nos. 1-23) at response to Interrogatory No. 14, Respondents' Liebel-Flarsheim Company, Inc.'s, Mallinckrodt Inc.'s (NY) and Mallinckrodt Inc.'s (Del.) Responses to Complainant Medrad's Second Set of Interrogatories (Nos. 24-57) at responses to Interrogatory Nos. 35-38, 40-42 and 44, and the Report of Robert A. Bell, Ph.D. Under Ground Rule 4 (viii).

n. On information and belief, during prosecution of the '602 reissue patent, Medrad and/or individuals on Medrad's behalf knowing, willfully and deliberately failed to disclose to the USPTO a complete English translation of Japanese patent 1-223943 even though such a complete English translation was produced to Medrad in the ITC Action prior to June of 2001; and

o. On information and belief, during prosecution of the '602 reissue patent, Medrad and/or individuals on behalf of Medrad knowingly, willfully and deliberately misrepresented the facts, and when Medrad learned of the facts, regarding Medrad's offer for sale and sale to Squibb Diagnostics of

MRI injectors that anticipated the claims of the '036 patent, the '648 reissue patent and the '602 reissue patent.

33. On information and belief, had Medrad and/or individuals on Medrad's behalf, including Gregory L. Bradley, Esq., not knowingly, willfully and deliberately failed to disclose and misrepresent the facts to the USPTO set out in paragraphs (a)-(o), the '036 patent, '648 reissue patent and '602 reissue patent would not have issued.

34. On information and belief, the USPTO Examiner justifiably relied upon the knowing, willful and deliberate omissions and misrepresentations of the facts set out in paragraphs (a)-(o) by Medrad and/or individuals on behalf of Medrad, including Gregory L. Bradley, Esq., when granting the '036 patent, '648 reissue patent, and '602 reissue patent.

35. On information and belief, Medrad, including Gregory L. Bradley, Esq., was aware during the prosecution of the '036 patent, the '648 reissue patent and/or the '602 reissue patent of the facts set out in paragraphs (a)-(o) and still knowingly, willfully and deliberately failed to disclose and misrepresented them to the USPTO because it knew that had it disclosed them the '036 patent, '648 reissue patent and '602 reissue patent would not have issued.

36. On information and belief, the '036 patent, '648 reissue patent and '602 reissue patent issued only as a result of a knowing, willful and deliberate scheme of omissions and misrepresentations of fact to the USPTO set out in paragraphs (a)-(o) orchestrated on behalf of Medrad by Gregory L. Bradley, Esq. either alone or in concert with other Medrad employees, representatives, and agents.

COUNTERCLAIM

Defendants, L-F Healthcare, Mallinckrodt, and L-F, through their attorneys, hereby allege as follows:

37. This counterclaim is for monopolization and attempted monopolization arising under Section 2 of the Sherman Act, Title 15, United States Code and for a declaratory judgment declaring the >203 patent, the >718 patent, and the >602 reissue patent invalid, unenforceable, not infringed, and that L-F has intervening rights and arises under the patent laws of the United States, 35 U.S.C. ' 1, *et seq.* and the Federal Declaratory Judgment Act, 28 U.S.C. ' 2201, et seq.

38. Jurisdiction of this Court over Count I of this Counterclaim is based upon 15 U.S.C. ' 4 (equitable relief), 15 U.S.C. ' 15 (treble damage relief), 15 U.S.C. ' 26 (equitable relief), and 28 U.S.C. ' ' 1331 and 1337, and upon Rule 13 of the Federal Rules of Civil Procedure. Jurisdiction of this Court over Count II of this Counterclaim is based upon 28 U.S.C. ' ' 1331, 1338(a), 2201, and 2202, and upon Rule 13 of the Federal Rules of Civil Procedure.

39. Venue in this Court is proper pursuant to 15 U.S.C. ' ' 15, 22, and 26, and 28 U.S.C. ' ' 1391 and 1440(b), and plaintiff, by virtue of having brought suit against L-F, has submitted itself to the jurisdiction of this Court.

COUNT I

SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. ' 2; MONOPOLIZATION AND ATTEMPTED MONOPOLIZATION OF THE MARKET FOR PATIENT INFUSION SYSTEMS FOR USE WITH MRI

40. The allegations of paragraphs 28-39 are incorporated herein by reference as though fully set forth herein.

41. On information and belief, Medrad was the owner of the >036 patent which is entitled "Patient Infusion System For Use With MRI.@ The >036 patent issued on February 27, 1996 from an original application filed with the USPTO on November 26, 1993.

42. The >036 patent is directed to a vascular injection system for use in connection with magnetic resonance imaging (MRI) procedures. MRI technology, introduced into clinical medical practice in the early 1980s, employs strong magnetic fields and radio frequency (RF) signals to produce high-resolution images of body tissue structure. MRI distinguishes normal tissues from abnormal tissues, and it is useful for diagnosing and tracking diseases affecting the brain, central nervous system, neck and large joints (knee, shoulder, hip). MRI is also often preferred for use in detecting soft tissue disorders, for example, musculoskeletal, liver, kidney, breast and gastrointestinal disorders.

43. The vascular injection system disclosed in the '036 patent, the >648 reissue patent, and the >602 reissue patent is a medical injector used in the controlled injection of a MRI contrast agent, which is a pharmaceutical injected into the body of a patient that is used to enhance the image obtained in certain diagnostic procedures, namely magnetic resonance imaging. The vascular injection system disclosed in the '036 patent, the >648 reissue patent, and the >602 reissue patent includes an injector (to which syringes

holding the contrast agent are secured) and a separate injection control unit, both of which are located in the MRI scan room. A system controller is located in the MRI operation room adjacent the scan room and is connected to the injection control unit by communication link.

44. On information and belief, Medrad manufactures, markets and sells in the United States a medical injector for use in connection with MRI procedures, which Medrad markets under the name Spectris MR Injector, and which medical injector Medrad asserts is manufactured in accordance with the disclosure of the '036 patent, the >648 reissue patent, and the >602 reissue patent. The Spectris MR Injector received FDA approval in 1995, and Medrad introduced it in the United States in the spring of 1996.

45. In January of 2000, L-F and Mallinckrodt began marketing in the United States a medical injector for use in MRI procedures, which L-F and Mallinckrodt market under the name Optistar™ MR Contrast Delivery System. L-F and Mallinckrodt received premarket approval from the FDA for marketing the Optistar™ MR Contrast Delivery System in the United States. L-F and Mallinckrodt import into the United States certain of the components for the Optistar™ MR Contrast Delivery System from Nemoto Kyorindo Co., Ltd., a Japanese company (hereinafter ANemoto@).

46. Until L-F and Mallinckrodt received FDA approval to market the Optistar™ MR Contrast Delivery System in the United States, the Medrad Spectris MR Injector was the only medical injector for use in connection with MRI procedures that had received approval from the FDA for marketing in the United States, and it was the only medical injector for use in connection with MRI procedures that had been sold in the United States. Other than the Optistar™ MR Contrast Delivery System, the Medrad Spectris MR Injector remains the only medical injector for use in connection with MRI procedures that

has received approval from the FDA for marketing in the United States and that is sold in the United States.

47. On information and belief, Medrad is the dominant supplier in the market for medical injectors for use in connection with MRI procedures in the United States, with the only competitor being L-F and Mallinckrodt with the Optistar™ MR Contrast Delivery System.

48. On information and belief, during prosecution of the '036 patent, Medrad knowingly, willfully, and deliberately omitted and misrepresented facts material to the prosecution of the '036 patent to the USPTO, which omissions and misrepresentations were made with the intent to mislead and/or deceive the USPTO examiner to obtain, maintain or increase Medrad's monopoly power.

49. Specifically, and among other things, on information and belief, Medrad knowingly, willfully and deliberately misrepresented and failed to disclose to the USPTO prior and commercial public uses and knowledge of products, and prior publications, anticipating and rendering obvious claims of the >036 patent, including, but not limited to, prior and commercial public use of the injector system identified and/or referred to in the 1991 publication, Saini et al., A*Technical Report: In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media*@, Investigative Radiology, vol. 26/No. 8, Aug. 1991, pp. 748-751.

50. Specifically, and among other things, on information and belief, Medrad knowingly, willfully and deliberately failed to fully inform the USPTO of the public use by Medrad of an MRI contrast delivery system more than one year before the filing date of the '036 patent as disclosed in the 1992 publication, A*Detection of Acute Avascular*

Necrosis of the Femoral Head in Dogs: Dynamic Contrast-Enhanced MR Imaging vs Spin-Echo and Stir Sequences@, found in AJR: 159, pp. 1255-1261, Dec. 1992; and of the medical injector system for use in MRI procedures developed by Medrad for display and/or displayed at the 1988 Radiological Society of North America Trade Show as referred to in *AMarket Scan@*, Diagnostic Imaging, Sep. 1988, p. 61.

51. Specifically, and among other things, on information and belief, Medrad knowingly, willfully and deliberately failed to disclose to the USPTO numerous public uses and public knowledge of the MRI injectors being claimed more than one year before the filing date of the '036 patent.

52. On information and belief, had Medrad not knowingly, willfully and deliberately failed to disclose and misrepresent the aforementioned facts to the USPTO, the '036 patent would not have issued.

53. On information and belief, the USPTO examiner justifiably relied upon Medrad=s knowing, willful and deliberate omissions and misrepresentations of the aforementioned facts when granting the '036 patent.

54. On information and belief, Medrad was aware during the prosecution of the '036 patent of thc aforementioned facts and still knowingly, willfully and deliberately failed to disclose and misrepresented them to the USPTO because it knew that had it disclosed the aforementioned facts the '036 patent would not have issued.

55. On information and belief, and in further effort to obtain, maintain or increase its monopoly power, on or about February 23, 1998, Medrad filed with the USPTO an application for reissue of the '036 patent, which reissue application issued as the >648 reissue patent on April 11, 2000.

56. On information and belief, during prosecution of the '648 reissue patent, Medrad also knowingly, willfully, and deliberately omitted and misrepresented facts material to the prosecution of the '648 reissue patent to the USPTO, which omissions and misrepresentations were made with the intent to mislead and/or deceive the USPTO examiner to obtain, maintain or increase Medrad's monopoly power.

57. Specifically, and among other things, although Medrad now cited to the USPTO the 1991 publication, Saini et al., A*Technical Report: In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media*@, Investigative Radiology, vol. 26/No. 8, Aug. 1991, pp. 748-751, upon information and belief, Medrad knowingly, willfully and deliberately failed to disclose to the USPTO that the medical injector that was the subject of the article was a Medrad Mark V medical injector, which included two syringes, and Medrad failed to disclose to the USPTO that the communication link between the system controller and medical injector powerhead was substantially non-reactive with the magnetic field of the imaging system as Medrad now asserts that term means.

58. Specifically, and among other things, on information and belief, Medrad knowingly, willfully and deliberately failed to disclose to the USPTO that Medrad MRI contrast delivery systems installed more than one year before the filing date of the '036 patent had a communication link between the system controller and the injection control until that was adapted to be substantially non-reactive with the magnetic field of the imaging system as Medrad now asserts that term means.

59. Specifically, and among other things, on information and belief, Medrad knowingly, willfully and deliberately failed to disclose to the USPTO that Medrad

products anticipating claims 1-7 of the >036 patent were in public use and were public knowledge more than one year before the filing date of the '036 patent.

60. On information and belief, had Medrad not knowingly, willfully and deliberately failed to disclose and misrepresent the aforementioned facts to the USPTO, the '648 reissue patent would not have issued.

61. On information and belief, the USPTO examiner justifiably relied upon Medrad=s knowing, willful and deliberate omissions and misrepresentations of the aforementioned facts when granting the '648 reissue patent.

62. On information and belief, Medrad was aware during the prosecution of the '648 reissue patent of the aforementioned facts and still knowingly, willfully and deliberately failed to disclose and misrepresented them to the USPTO because it knew that had it disclosed the aforementioned facts the '648 reissue patent would not have issued.

63. On information and belief, in a further effort to obtain, maintain or increase its monopoly power, on April 25, 2000, Medrad brought an action in the United States International Trade Commission, Investigation No. 337-TA-434, against L-F, Mallinckrodt and Nemoto for alleged unfair trade practices as a result of the purported infringement by L-F, Mallinckrodt and Nemoto of the '648 Reissue Patent through the importation of components for the Optistar™ MR Contrast Delivery System (hereinafter "ITC Action").

64. On information and belief, Medrad brought the ITC action in bad faith and with knowledge that the '648 reissue patent is invalid and was obtained through fraudulent conduct, and that L-F, Mallinckrodt and Nemoto did not infringe any of the claims of the '648 reissue patent. The ITC action was objectively baseless and, upon information

and belief, was brought solely to interfere directly with L-F, Mallinckrodt, and Nemoto=s businesses.

65. On information and belief, in a still further effort to obtain, maintain or increase its monopoly power, on April 25, 2000, Medrad also brought an action in the United States District Court for the Western District of Pennsylvania, Civil Action No. 00-799, against L-F, Mallinckrodt, and Nemoto for alleged infringement by L-F, Mallinckrodt, and Nemoto of the '648 reissue patent through the manufacture, importation, offer for sale and sale of the Optistar™ MR Contrast Delivery System (hereinafter "Pennsylvania Action").

66. On information and belief, Medrad brought the Pennsylvania action in bad faith and with knowledge that the '648 reissue patent is invalid and was obtained through fraudulent conduct, and that L-F, Mallinckrodt and Nemoto did not infringe any of the claims of the '648 reissue patent. The Pennsylvania action was objectively baseless and, upon information and belief, was brought solely to interfere directly with L-F, Mallinckrodt, and Nemoto=s businesses.

67. On or about February 12, 2001, the ITC Action was terminated when the Commission entered an order declining to review an Initial Determination entered by the Administrative Law Judge on September 26, 2000, which Initial Determination held the '648 reissue patent invalid as a result of Medrad's failure to comply with the procedures governing reissue patents. On March 2, 2001, Medrad filed a Notice of Dismissal without prejudice in the Pennsylvania Action.

68. On information and belief, in a still further effort to obtain, maintain or increase its monopoly power, Medrad filed with the USPTO an application for reissue of the

'648 reissue patent on or about November 16, 2000, which reissue application issued as the >602 reissue patent on March 26, 2002

69. On information and belief, during prosecution of the '602 reissue patent, Medrad again knowingly, willfully, and deliberately omitted and misrepresented facts material to the prosecution of the '602 reissue patent to the USPTO, which omissions and misrepresentations were made with the intent to mislead and/or deceive the USPTO examiner to obtain, maintain or increase Medrad's monopoly power.

70. Specifically, and among other things, upon information and belief, Medrad continued to knowingly, willfully and deliberately fail to disclose to the USPTO that the medical injector that was the subject of the 1991 publication, Saini et al., A*Technical Report: In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media*@, Investigative Radiology, vol. 26/No. 8, Aug. 1991, pp. 748-751, was a Medrad Mark V medical injector, which included two syringes, and Medrad failed to disclose to the USPTO that the communication link between the system controller and medical injector powerhead was substantially non-reactive with the magnetic field of the imaging system as Medrad now asserts that term means.

71. Specifically, and among other things, on information and belief, Medrad knowingly, willfully and deliberately continued to fail to disclose numerous public uses and instances of public knowledge known to it.

72. Specifically, and among other things, on information and belief, Medrad knowingly, willfully and deliberately continued to fail to disclose to the USPTO that a Medrad MR contrast delivery system installed more than one year before the filing date of

the '036 patent had a communication link that was adapted to be substantially non-reactive with the magnetic field of the imaging system as Medrad now asserts that term to mean.

73. On information and belief, had Medrad not knowingly, willfully and deliberately failed to disclose and misrepresent the aforementioned facts to the USPTO, the '602 reissue patent would not have been allowed.

74. On information and belief, the USPTO examiner justifiably relied upon Medrad=s knowing, willful and deliberate omissions and misrepresentations of the aforementioned facts when allowing the '602 reissue patent.

75. On information and belief, Medrad was aware during the prosecution of the '602 reissue patent of the aforementioned facts and still knowingly, willfully and deliberately failed to disclose and misrepresented them to the USPTO because it knew that had it disclosed the aforementioned facts the '602 reissue patent would not have been allowed.

76. On information and belief, in a still further effort to obtain, maintain or increase its monopoly power, Medrad filed the instant action on December 5, 2001, alleging infringement of the '203 patent. Medrad brought this action in bad faith and with knowledge that the'203 patent is not infringed by L-F. The action was and is objectively baseless and, upon information and belief, was brought solely to interfere directly with L-F's business.

77. On information and belief, in a still further effort to obtain, maintain or increase its monopoly power, Medrad filed an amended complaint on January 16, 2002, to allege infringement of the '718 patent. Medrad brought this action in bad faith and with knowledge that the '718 patent is invalid and was obtained through fraudulent conduct, and that L-F did not infringe any of the claims of the '718 patent. This action was and is

objectively baseless and, upon information and belief, was brought solely to interfere directly with L-F's business.

78. For the purposes of this Count I, the relevant product market is medical injectors for use in MRI procedures and the relevant geographic market is the United States.

79. As a result of the aforementioned actions of Medrad, Medrad has monopolized and attempted to monopolize the relevant market in violation of Section 2 of the Sherman Act. Medrad has the power to control the price of medical injectors for use in MRI procedures and has improperly acquired and maintained that power through the aforementioned knowing, willful and deliberate omissions and misrepresentations of facts to the USPTO. This monopoly power has been used by Medrad to exclude entry into the market, and to exclude, regulate, and restrain competition in the relevant market at issue in this case.

80. On information and belief, Medrad willfully engaged in the aforementioned conduct with the intent of acquiring and maintaining its monopoly power in the relevant market. Medrad engaged in the aforementioned conduct for predatory, anti-competitive, exclusionary and willful purposes, and for no legitimate business justification or purpose. Among other things, on information and belief, Medrad has unreasonably created artificial barriers to entry into the relevant market at issue in this case, and has unreasonably increased L-F's and Mallinckrodt=s costs and the costs of any other competitor in the manufacture, sale and distribution of products in the relevant market at issue in this case.

81. Medrad=s acts have produced and will continue to produce the following anti-competitive effects, among others:

(a) Competition in the manufacture, sale and distribution of products in the relevant market at issue in this case has been, and will be, unreasonably restrained and eliminated, and has been, and will be, monopolized by Medrad;

(b) Prices for products in the relevant market at issue in this case have been, and will continue to be, substantially higher than prices that would prevail in a competitive market;

(c) Barriers to entry in the relevant market have been and will be, raised to levels that are insurmountable, assuring that Medrad will maintain, or increase, its monopoly power; and

(d) Innovation and development in the relevant market and related markets has been, and will continue to be, stifled.

82. As a direct and proximate result of Medrad=s unlawful acts, L-F and Mallinckrodt have been injured in their business and property, were forced to defend the ITC Action, the Pennsylvania Action and this action at great expense, are threatened with immediate and irreparable additional loss and harm, and will continue to be so threatened unless Medrad is enjoined from continuing its illegal, unfair and predatory acts.

COUNT II
DECLARATORY JUDGMENT OF PATENT INVALIDITY, UNENFORCEABILITY, INTERVENING RIGHTS, AND NONINFRINGEMENT

83. The allegations of paragraphs 28-82 are incorporated herein by reference as though fully set forth herein.

84. Plaintiff claims to be the assignee of the >203 patent, the >718 patent, the >602 reissue patent and has brought suit against L-F herein for alleged infringement of the >203 patent, the >718 patent, and the >602 reissue patent.

85. An actual case or controversy exists between plaintiff and L-F based upon plaintiff having filed the Second Amended Complaint against L-F.

86. Neither L-F nor any of its respective customers has infringed any of the claims of the >203 patent, the >718 patent, or the >602 reissue patent.

87. Upon information and belief, and as will likely be supported by evidence after reasonable opportunity for further investigation and discovery, the claims of the >203 patent asserted against L-F in this action are invalid, null, and/or void for failure to comply with the conditions and requirements for patentability specified in Title 35, U.S.C., including, but not limited to, 35 U.S.C. '' 102, 103 and/or 112.

88. Upon information and belief, and as will likely be supported by evidence after reasonable opportunity for further investigation and discovery, the >718 patent is invalid, null, and/or void for failure to comply with the conditions and requirements for patentability specified in Title 35, U.S.C., including, but not limited to, 35 U.S.C. '' 102, 103 and/or 112.

89. Upon information and belief, and as will likely be supported by evidence after reasonable opportunity for further investigation and discovery, the >602 reissue patent is invalid, null, and/or void for failure to comply with the conditions and requirements for patentability specified in Title 35, U.S.C., including, but not limited to, 35 U.S.C. '' 102, 103, 112 and/or 251.

90. L-F and Mallinckrodt is offering for sale and selling the Optistar™ MR Contrast Delivery System, which Medrad charges with infringing claims of the '203, '718 and '602 reissue patents.

91. Medrad has commenced this and other lawsuits against L-F to maintain, or to increase, its monopoly power, based upon alleged infringement of patents related to products for use in the relevant market and related markets.

92. As a result of the aforesaid conduct of Medrad, there is an actual controversy pursuant to 28 U.S.C. ' 2201 regarding the validity, enforceability, intervening rights and infringement of the claims of the '203, '718 and '602 reissue patents.

93. The '718 and '602 reissue patents are unenforceable and invalid due to inequitable and/or fraudulent conduct during the prosecution as set forth with particularity above.

94. Any claim by Medrad that L-F infringes, contributorily infringes or is inducing infringement of any of the claims of the '602 reissue patent is barred by the doctrine of intervening rights as set forth in 35 U.S.C. ' 252.

96. L-F has been injured and damaged by plaintiff=s filing of the Second Amended Complaint in the present action asserting patents that are invalid and not infringed.

PRAYER FOR RELIEF

WHEREFORE, Tyco Healthcare Group LP, Mallinckrodt, Inc. and Liebel-Flarsheim Company (referred to collectively as "L-F") pray that:

1. Plaintiff=s Second Amended Complaint be dismissed with prejudice and that judgment be entered for L-F.

2. With respect to Count I of the Counterclaim,

A. A judgment be entered awarding them damages in an amount sufficient to compensate for all harm caused by the conduct of Medrad including the costs incurred by L-F and Mallinckrodt in defending the ITC Action, the Pennsylvania Action and this action;

B. An order be entered trebling the amount of compensatory damages pursuant to Section 4 of the Clayton Act, 15 U.S.C. ' 15;

C. An order be entered granting permanent injunctive relief as may be reasonably necessary or appropriate to eliminate the effects of Medrad=s violations of the antitrust laws and to restore effective competition in the manufacture, sale and distribution of medical injectors for use in MRI procedures;

D. A judgment be entered awarding L-F punitive damages as authorized by law.

3. With respect to Count II of the Counterclaim,

A. A declaratory judgment be entered declaring that the >203 patent is invalid;

B. A declaratory judgment be entered declaring that the >718 patent is invalid;

C. A declaratory judgment be entered declaring that the >602 reissue patent is invalid;

D. A declaratory judgment be entered declaring that the '718 patent is unenfoceable.

E. A declaratory judgment be entered declaring that the >602 reissue patent is unenforceable;

F. A declaratory judgment be entered declaring that L-F has the right to make, use, sell, offer to sell and import into the United States the Optistar™ MR Contrast Delivery System and components therefor free from any claim of infringement of the '602 reissue patent under the doctrine of intervening rights pursuant to 35 U.S.C. ' 252;

G. A judgment be entered declaring that L-F nor any of its customers has infringed any of the claims of the '203 patent;

H. A judgment be entered declaring that neither L-F nor any of its customers has infringed any of the claims of the '718 patent;

I. A judgment be entered declaring that L-F nor any of its customers has infringed any of the claims of the '602 reissue patent;

J. This case be adjudged and decreed exceptional under 35 U.S.C. ' 285 entitling L-F to an award of its reasonable attorney fees and that such reasonable attorney fees be awarded

4. That L-F be awarded its costs and prejudgment interest on all damages;

5. That Medrad be required to file with the court within thirty (30) days after entry of the final judgment of this cause of action a written statement under oath setting forth in detail the manner in which Medrad has complied with the judgment; and

6. For such other and further relief as the Court deems just and proper.

Respectfully submitted,

TYCO HEALTHCARE GROUP LP
MALLINCKRODT INC.
LIEBEL-FLARSHEIM COMPANY

Dated: July 8, 2002

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing **DEFENDANTS,' TYCO HEALTHCARE GROUP LP, MALLINCKRODT, INC. AND LIEBEL-FLARSHEIM CO., ANSWER AND COUNTERCLAIMS TO SECOND AMENDED COMPLAINT** were served this 8th day July, 2002, on the following counsel of record in the following manner:

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